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APPLICANT:

Cupp et al.

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K. Hendricks

INVENTION:

"DENTAL CARE PET FOOD"

Hon. Assistant Commissioner for Patents Washington, D.C. 20231

APPELLANTS' REPLY BRIEF

Sir:

INTRODUCTION I.

PECENNEL POOR TO THE POOR TO T Appellants submit Appellants' Reply Brief in response to the Examiner's Answer dated July 31, 2001 pursuant to 37 C.F.R. § 1.193(b)(1). Appellants respectfully submit the Examiner's Answer has failed to remedy the deficiencies noted in Appellants' Appeal Brief filed on May 21, 2001 with respect to the Final Office Action dated January 2, 2001 for the reasons set forth below. Accordingly, Appellants respectfully request that the rejection of the pending claims be reversed.

II. THE REJECTION OF CLAIMS 1, 13, 20 AND 24 <u>UNDER §112 IS NOT PROPER</u>

Appellants respectfully submit that the rejection of Claims 1, 13, 20 and 24 under §112, first paragraph is improper. Contrary to the Patent Office's position, the claim term "at least 2% by weight of insoluble fiber" of Claims 1, 13, 20 and 24 is clearly supported by the Specification so as to reasonably convey to one skilled in the relevant art that Appellants, at the time the application was filed, had possession of the claimed invention.

At the outset, Appellants question how the Patent Office can even argue that the lower limit of the claim range, e.g., at least 2%, is not supported by the Specification. Surely, this lower range limit is clearly supported by the Specification as reasonably conveyed to one of ordinary skill in the art. Contrary to the Patent Office's assertions, the term "about 2%" as it appears throughout the originally filed Specification is clearly sufficient in scope and meaning to support the range limit of "at least 2%". Further, the term "insoluble fiber" appears in the Specification, for example, on page 2, at lines 31-34 without reference to limitations as to the amount thereof. Moreover, independent Claims 1, 13 and 20, as originally filed, required a dried pet food that included a matrix having an insoluble fiber, again without limitations to the amount thereof. Thus, the Specification, as originally filed, clearly supports the claimed range limit of "at least 2%."

With respect to the issue that there is no upper limit as to the amount of the insoluble fiber, Appellants again believe that this claimed feature is clearly supported by the Specification. As previously discussed, independent Claims 1, 13 and 20, as originally filed, recited a dried pet food that included an insoluble fiber with no upper limit, let alone no lower limit, with respect to the amount of the insoluble fiber. Contrary to the Patent Office's position, the "about 15% by weight insoluble fiber" as disclosed in the Specification should not be construed as an upper limit for the content of the insoluble fiber. The use of the terms "preferably" and "conveniently" in conjunction with the term "about 2% to about 15% by weight insoluble fiber" clearly indicates that the term "about 15%" should, at most, be construed as a preferred upper limit but not the sole upper limit with respect to the content of the insoluble fiber.

Therefore, Appellants believe that the Specification clearly conveys to one skilled in the art that the amount of insoluble fiber in the dried pet food of the claimed invention can be construed to exceed 15% by weight. Moreover, the dried pet food of the claimed invention

includes other components in addition to insoluble fiber. As disclosed in the Specification on page 4, the protein source and carbohydrate source can be included in a variety of different amounts. For example, the dried pet food can include about 12% to about 50% of a protein source by weight and about 20% to about 65% of a carbohydrate source by weight in addition to insoluble fiber. See, Specification, page 4. Therefore, Appellants believe that one skilled in the art would understand that the Specification clearly supports an amount of insoluble fiber that can exceed "about 15% by weight".

Accordingly, Appellants believe that the Examiner's purported interpretation of the claims which limits the amount of insoluble fiber to an upper limit of about 15% is clearly improper.

III. THE ANTICIPATION REJECTIONS IN VIEW OF SIMONE OR GELLMAN ARE IMPROPER

Appellants respectfully submit that the anticipation rejections in view of *Simone* or *Gellman* are improper. Appellants believe that the Examiner has mischaracterized the teachings of these references. Therefore, Appellants do not believe that either one of these references teaches or arguably suggests a number of features of the claimed invention.

A. Simone Is Deficient With Respect to the Moisture Content, Insoluble Fiber Content and Dried Food Features

With respect to *Simone*, Appellants respectfully submit that the Patent Office has mischaracterized the teachings of *Simone* regarding the moisture content, dried pet food and insoluble fiber content features of the claimed invention. Contrary to the Patent Office's position, *Simone* fails to teach or arguably suggest a moisture content of less than 10% by weight as required by the claimed invention. What *Simone* clearly emphasizes is that an extruded pet food product and <u>not</u> a final processed product can have a moisture content of about 10% to about 35%.

In this regard, Appellants do not believe that one skilled in the art viewing *Simone* would necessarily equate the moisture content of the extruded product to the product that has been completely processed. Contrary to the Patent Office's position, further drying of the extruded product does not necessarily take place as the extruded product is cooled to form the final processed product. Quite conceivably, the extruded product could retain an increased level of moisture as it is cooled depending on the process conditions. Indeed, *Simone* merely indicates that the extruded product is dried and cooled at a controlled temperature. Thus, *Simone* fails to place any conditions on the humidity level of the media (e.g., air) within which the drying and cooling stages would necessarily occur.

If the cooling and drying stages were conducted in ambient air (where *Simone* does not suggest otherwise), for example, the level of humidity of ambient air could be such that the extruded product could necessarily retain more moisture as it is cooled due to, for example, condensation or absorption such that a moisture level of less than 10% could not be achieved. Indeed, the only example that *Simone* provides is for a decrease in moisture content from 28.01% to 20% after drying and cooling of the extruded product in ambient air for an hour. See, *Simone*, col. 8, lines 20-25. This clearly fails to suggest that a 10% moisture level is achievable, especially considering that *Simone* fails to suggest the control of humidity during the cooling and drying of its extruded product. Therefore, Appellants believe that *Simone* merely conveys to one skilled a moisture content of greater than 12%. See, *Simone*, col. 5, lines 5-10.

Moreover, *Simone* teaches that its pet product has a high fiber content in order to absorb moisture and make the product more chewable. In contrast, Appellants have surprisingly discovered that a dry pet food, in part, having a moisture content of less than 10%, can significantly reduce the brittleness of pet food without compromising on the hardness that is needed to accomplish mechanical cleaning by abrasion to facilitate the cleaning of a pet's teeth.

Thus, Appellants do not believe that one of ordinary skill in the art would regard *Simone* as teaching a pet food product that has a moisture content of less than 10% as required by the claimed invention.

In addition to the moisture content, Appellants do not believe that *Simone* teaches or arguably suggests a pet product that has, in part, an insoluble fiber content ranging from about 2% to about 15% as required by independent Claim 8. Contrary to the Patent Office's purported insoluble fiber content calculations, the insoluble fiber content as taught by *Simone* is well above the 15% level as required by the claimed invention. In this regard, the Patent Office asserts that the final product of *Simone* could necessarily have an insoluble fiber content of about 7.8%. This is based on the Patent Office's purported reasoning that the cellulosic component of *Simone*'s pet product, namely, corn flour, has an inherent insoluble fiber content of 15%. Thus, the Patent Office further reasons that the *Simone* product which contains 50% by weight of the cellulosic component would necessarily have an insoluble fiber content of approximately 7.8%. See, Examiner's Answer, page 5.

However, the focus of *Simone* with respect to the cellulosic component does not relate to corn flour but to <u>corn cob fractions</u>. See, *Simone*, column 3, lines 4-35. It is generally known that the corn cob is the central rachis or core to which the individual corn kernels are attached, and which remains an agricultural waste after threshing. See, *Kent. et al.*; Technology of Cereals; Pergamon UK; 1994, p. 305 attached hereto as Exhibit A. Further, it is generally accepted that corn cobs have a much higher cellulose content than corn kernels which in turn are known to have a higher cellulose content than their corn flour product. This makes sense as corn flour is a considerably refined product.

Moreover, *Simone* clearly indicates that the corn cob fractions (e.g., fibrous materials, such as woody and shaft portions of the cob) are not digestible so as to provide increased

roughage and bulk to assist the pet in digestion of food. See, *Simone*, col. 3, lines 25-30. Thus, Appellants believe that the Examiner's purported calculations with respect to the insoluble fiber content of *Simone* are clearly erroneous. Accordingly, Appellants do not believe that one skilled in the art would clearly regard *Simone* as teaching an insoluble fiber content of 15% or greater.

With respect to the dried pet food feature of the claimed invention, Appellants do not believe that *Simone* teaches or arguably suggests same. Contrary to the Patent Office's assertions, the clear emphasis of *Simone* is to provide a chew pet product that is a meal supplement and thus <u>not</u> an entire meal as required by the dried pet food of the claimed invention. Just because the pet product of *Simone* is edible or can be eaten as asserted by the Patent Office, does not necessarily mean that its product can be considered a complete meal. Indeed, *Simone* clearly indicates that its chew pet product is given together with a diet of commercial canned dog food. See, *Simone*, col. 8, lines 26-34.

B. Gellman is Deficient With Respect to the Gelatinized Feature

With respect to *Gellman*, Appellants respectfully submit that this reference fails to teach or arguably suggest a number of features of the claimed invention in addition to the insoluble fiber content feature as required by the claimed invention. Contrary to the Patent Office's assertions, *Gellman* fails to anticipate the claimed invention regardless of the fact that it fails to disclose the insoluble fiber content of the claimed invention as even admitted by the Patent Office.

For example, Appellants do not believe that *Gellman* teaches or suggests the gelatinized feature of the claimed invention. In this regard, *Gellman* employs relatively mild process conditions to formulate its soft biscuit as compared to process conditions typically associated with gelatinization. It is generally accepted that the onset of gelatinization requires a temperature of about 60°C (140°F). See, Exhibit A, p. 61.

In contrast, *Gellman* discloses process conditions that include maximum pressures of 75 p.s.i. (about 5.5 atmospheres) and temperatures ranging from ambient to 110°F. See, *Gellman*, col. 9, lines 15-28. Moreover, *Gellman* clearly indicates that an essential feature of the invention is that processing is conducted under low shear and/or low pressure process conditions. *Gellman* further states that the use of high shear and/or high pressure conditions will decimate or smear the meat and meat-containing particles that are essential to the invention. See, *Gellman*, Co. 9, lines 21-28. Thus, Appellants do not believe that one skilled in the art viewing *Gellman* would regard same as teaching the gelatinized features of the dried pet food of the claimed invention.

IV. CONCLUSION

For the foregoing reasons Appellants respectfully submit that the Examiner's Answer does not remedy the deficiencies noted in Appellants' Appeal Brief with respect to the final rejection. Therefore, Appellants respectfully once again request that the Board of Appeals reverse the rejections.

Respectfully submitted,

(Reg. No. 30,142)

Thomas C. Basso, Esq.

BELL, BOYD & LLOYD LLC

P.O. Box 1135

Chicago, Illinois 60690-1135 Telephone: 312/807-4310

Attorney for Applicants

Exhibit A

TECHNOLOGY OF CEREALS

AN INTRODUCTION FOR STUDENTS OF FOOD SCIENCE AND AGRICULTURE

FOURTH EDITION

N. L. KENT

Sometime Scholar of Emmanuel College, Cambridge Formerly at the Flour Milling and Baking Research Association, St. Albans and Chorleywood

and

A. D. EVERS

Flour Milling and Baking Research Association, Charleywood



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KENT'S TECHNOLOGY OF CEREALS

















Pergamon

FEED AND INDUSTRIAL USES FOR CEREALS

305

weeks) and developers (13-18 weeks), 48% for laying hens (Nakaue and Arscott, 1991).

For horses, 25-39% of the feed could be cracked maize, along with 45-30% of rolled and 7-10% of wheat bran (Opt, 1991).

By-products of the milling of maize are also used for animal feeding. A product known as hominy feed comprises the entire by-product streams from the dry milling of maize. It is a relatively inexpensive high-fibre, high-calorie material which is high in carotenoids (yellow pigments desirable for chicken feed) and vitamins A and D. Hominy feed is an excellent source of energy for both ruminants and monogastric animals, in this respect being equal or superior to whole maize. Hominy feed competes with other maize by-products — corn gluten feed and spent brewers' grains — as an animal feed. Hominy feed may partially replace grain in diets for horses, provided the feed is pelleted (Ott, 1991). Gluten feed is recovered from the steeping water in which maize is steeped as a stage in wetmilling (q.v.). After the separation of the germ, in the wet-milling of maize, and extraction of the oil, the residue — germ cake — is used for cartle

Maize cobs

The maize cob (corn cob in the U.S.A.) is the central rachis of the female inflorescence of the plant to which the grains are attached, and which remains as agricultural waste after threshing. As about 180 kg of cobs (d.b.) are obtained from each tonne of maize shelled, the annual production of cobs in the U.S.A. alone is of the order of 30 million tonnes.

Cobs consist principally of cellulose 35%, pentosans 40% and lignin 15%. Agricultural uses for maize cobs, listed by Clark and Lathrop (1953), include litter for poultry and other animals; mulch and soil conditioner; animal and poultry feeds. The feeding value of corncobs is about 62% of that of grains. Up to 67% of ground corncobs, with 14% of ground shelled maize and some soyabean meal and molasses-urea provided a suitable feed for cattle. For poultry, a feed containing corncob meal plus ground maize is

preferred to one in which ground maize is the sole cereal because it results in better plumage, less feather-picking, and less cannibalism. On the other hand, the corncob plus maize feed gives a reduced egg production and less body-weight gain (Clark and Lathrop, 1953).

Barley for animal feed

Apart from its use in malting, brewing and distilling (c.f. Ch. 9), the next most important use for barley is as food for animals, particularly pigs, in the form of barley meal.

As whole barley contains about 34% of crude fibre, and is relatively indigestible, the preferred type of barley for animal feeding is one with a low husk content. Low protein barleys are favoured for malting and brewing, but barley of high protein content is more desirable for animal feed.

The total digestible nutrients in barley are given as 79%. Digestible coefficients for constituents of ground barley are 76% for protein, 80% for fat, 92% for carbohydrate and 56% for fibre (Morrison, 1947).

The feeding value of barley is said to be equal to that of maize for ruminants (Hockett, 1991) and 85-90% of that of maize for swine (Cromwell, 1991). For swine, barley can replace all the maize in the feed; indeed, barley is preferred to maize for certain animals, e.g. pigs. The feeding value of barley for pigs is improved by grinding, pelleting, cubing, rolling or micronizing (Hockett, 1991). It is also used extensively in compound feeds.

For poultry, a feed containing barley and maize improved egg production and feed efficiency as compared with either cereal fed alone (Lorenz and Kulp, 1991).

Swine fed barley grew faster and had a more efficient feed/gain ratio if the barley was pelleted than if fed as meal. Feed for pregnant sows and gilts can contain up to 85% of ground barley, up to 65% for lactating sows, 80% for growing pigs and 86% for finishing pigs (Cromwell, 1991).

The barley is normally fed either crushed or as a coarse meal, thereby avoiding wastage that could result from the passage of undigested grains through the alimentary tract. The widespread use proteins of wheat starch to have molecular masses of under 50 K while integral proteins were over 50 K. Altogether ten polypeptides have been separated between 5 K and 149 K. The major 59 K polypeptide is probably the enzyme responsible for amylose synthesis. It has been shown to be concentrated in concentric shells within granules. Two other polypeptides of 77 K and 86 K are likely to be involved in amylopectin synthesis. Perhaps the most interesting of the surface proteins is that in the 15 \bar{K} band. This has been found in greater concentration on starches from cereals with soft endosperm than on those from cereals with hard endosperm. The protein has been called 'friabilin', because of its association with a friable endosperm (cf Ch. 4) (Greenwell and Schofield, 1989).

Phosphorus is another important minor constituent of cereal starches. It occurs as a component of lysophospholipids. They consist of 70% lysophosphatidyl choline, 20% lysophosphatidyl ethanolamine and 10% lysophosphatidyl glycerol. The proportion of lysophospholipids to free fatty acids varies with species: in wheat, rye, triticale and barley over 90% occurs as lysophospholipids, in rice and oats 70% and in millets and sorghum 55%. In maize 60% occurs as free fatty acids (Morrison, 1985).

Removal of lipids from cereal starches reduces the temperatures of gelatinization-related changes and increases peak viscosity of pastes. In other words they become more like the lipid-free potato starch,

Technological importance of starch

Much of the considerable importance of starch in foods depends upon its nutritional properties; it is a major source of energy for humans and for domestic herbivorous and omnivorous animals. In the human diet it is usually consumed in a cooked form wherein it confers attractive textural qualities to recipe formulations. These can vary from those of gravies and sauces, custards and pie fillings to pasta, breads, cakes and biscuits (cookies). Much of the variation in texture depends upon the degree of gelatinization, which in turn depends upon the temperature, and the amount

of water available during cooking. Digestibility in the intestines of single-stomached animals is also increased by gelatinization.

Gelatinization

This is a phenomenon manifested as several changes in properties, including granule swelling and progressive loss of organized structure (detected as loss of birefringence and crystallinity), increased permeability to water and dissolved substances (including dyes), increased leaching of starch components, increased viscosity of the aqueous suspension and increased susceptibility to enzymic digestion.

At room temperature starch granules are not totally impermeable to water, in fact water uptake can be detected microscopically by a small increase in diameter. The swelling is reversible and the wetting and drying can be cycled repeatedly without permanent change. If the temperature of a suspension of starch in excess water is raised progressively, a condition is reached, around 60°C, at which irreversible swelling begins, and continues with increasing temperature. The change is endothermic and can be quantified by thermal analysis techniques.

Typical heats of gelatinization in J per g of dry starch are: wheat 19.7, maize 18.0, waxy maize 19.7 and high amylose maize 31.79 (Maurice et al., 1983). Swelling involves increased uptake of water and can thus lead to increased viscosity by reducing the mobile phase surrounding the granules; accompanying leaching of starch polymers into this phase can further increase viscosity. The swelling behaviour of starch heated in water is often followed using a continuous automatic viscometer, such as the Brabender Amylograph (Shuey and Tipples, 1980). Upon heating a slurry of 7-10% starch w/w in water at a constant rate of 1°-5°C per min, starch eventually gelatinizes and begins to thicken the mixture. The temperature at which a rise in consistency is shown is called the pasting temperature. The curve then generally rises to a peak, called the peak viscosity. When the temperature reaches 95°C, that temperature is maintained for 10-30 min and stirring is continued to determine the shear stability of

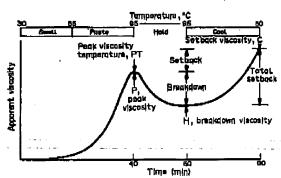


Fig 3.9 Chart showing characteristics recorded by the Brabender Amylograph.

the starch. Finally the paste is cooled to 30°C and the increase in consistency is called set-back. (Fig. 3.9)

Retrogradation (see also Ch. 8)

Suspensions of gelatinized granules containing more than 3% starch form a viscous or semi-solid starch paste which, on cooling, sets to a gel. Three dimensional gel networks are formed from the amylose-containing starches by a mechanism known as 'entanglement'. The relatively long amylose molecules that escape from the swollen granules into the continuous phase become entangled at a concentration of 1-1.5% in water. On cooling the entangled molecules lose translational motion, and the water is trapped in the network. Crystallites begin to form eventually at junction zones in the swollen discontinuous phase, causing the gel slowly to increase in rigidity (Osman, 1967). When starch gels are held for prolonged periods, reprogradation sets in. As applied to starch this means a return from a solvated, dispersed, amorphous state to an insoluble, aggregated or crystalline condition. Retrogradation is due largely to crystallization of amylose, which is much more rapid than that of amylopectin. It is responsible for hardening of cooked rice and shrinkage and syneresis of starch gels and possibly firming of bread, Although regarded as crystalline, retrograded gels are susceptible to amylolysis, however a fraction has recently been found that is resistant to enzyme attack. Known as resistant starch, it behaves as dietary fibre and is most abundant in autoclaved amylomaize starch suspensions (Berry, 1988).

Starch damage (see Chs 6 and 8)

Granule damage of a particular type alters the properties of starch in some ways similar to gelatinization. Defining the exact type of damage is difficult and this accounts for the continued use of the general term. The essential characteristics associated with damaged starch are somewhat similar to gelatinized granules, but there are differences also. Thus mechanical damage results

- 1. increased capacity to absorb water, from 0.5-fold starch dry mass when intact to 3-4-fold when damaged (gelatinized granules) absorb as much as 20-fold);
- increased susceptibility to amylolysis;
- 3. loss of organized structure manifested as loss of X-ray pattern, birefringence, differential scanning calorimetry gelatinization endotherm;
- reduced paste viscosity;
- 5. increased solubility, leading to leaching of mainly amylopectin. (In gelatinized granules, amylose is preferentially leached (Craig and Stark, 1984).)

At a molecular level the disorganization of granules appears to be accompanied by fragmentation of amylopectin molecules during damage whereas gelatinization achieves loss of organization without either polymer being reduced in size.

Controlling starch damage level during milling of wheat flour is important as it affects the amount of water needed to make a dough of the required consistency (see Ch. 7) (Evers and Stevens, 1985).

Cell walls

The older literature describes the components of cereal grain cell walls as pentosans and hemicelluloses. Pentosans are defined earlier in this chapter, but hemicelluloses are more difficult to define and indeed the term is even now only used loosely. Hemicelluloses were originally assumed